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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/380,324	12/08/1999	KLAUS CICHUTEK	10383/006001	2471

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

24.

Office Action Summary

Application No.

09/380,324

Applicant(s)

CICHUTEK ET AL.

Examiner

Joseph T. Voitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13-18,20-22,28 and 32-40 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) 13-18,21,22 and 32-34, 36--39 is/are allowed.
- 6) ☒ Claim(s) 20,28,35 and 40 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☒ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 national stage filing of PCT/DE98/00593, filed February 27, 1998, which claims benefit to foreign applications 19707971.7 filed February 27, 1997 and 19808438.2 filed February 27, 1998 both in Germany.

Applicants amendment filed February 17, 2004, has been received and entered. Claims 1-12, 19, 23-27, 29-31 have been canceled. Claims 15, 20, and 28 have been amended. Claims 36-40 have been added. Claims 13-22, 28 and 32-40 are pending and currently under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35 stands rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Initially, the amendment to claim 20 has obviated the basis of the rejection as it applies to the newly amended claim. More specifically, claim 20 has been amended to more generally set forth the claimed nucleic acid sequence instead of the specific vector pLβAc/env Tr712 neo.

With respect to claim 35, Applicants have neither amended the claim nor provided arguments in traverse of the rejection over claim 35. As set forth in the previous office action while the construction and characterization of the TelCeB6 by Cosset *et al.* was noted the availability of this particular cell line and the relevant plasmids are not provided as required for biological material as defined by 37 C.F.R. 1.801 (see previous office action, pages 5-6). The instantly claimed invention recites and therefore requires each of these specific plasmids. Because the claims recite the use of the various plasmids set forth in the claims the methods would require the use of these specific biological materials. Since the biological are essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the cell lines are not so obtainable or available, the requirements of 35 U.S.C. 112, regarding "how to make", may be satisfied by a deposit of cell lines. If the cell lines have been deposits are made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicant, or a statement by an attorney of record over his or her signature and registration number, stating that the specific plasmids have been deposited under the Budapest Treaty and that the cell lines will be irrevocably and without restriction released to the public upon the issuance of a patent, would satisfy the deposit requirement.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

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- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request of for the effective life of the patent, whichever is longer; and,
- (d) a test of viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Newly amended claims 20, 28 and 40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically,

Claim 20 recites the limitation “the full-length surface envelope gp120-SU” and “the transmembrane envelope protein resulting form a stop codon at position 712” in lines 2-4. There is insufficient antecedent basis for these limitations in the claim or in claim 17 on which it depends. Claim 17 does not even recite or require a truncated variant of a transmembrane envelope protein. More clearly setting forth antecedent basis in either claim 17 or 20 would address the basis of the rejection. In addition, it is unclear to what specific sequence and thus to what specific “position 712” refers.

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Claim 28 is vague and unclear in the recitation of “the vector mediates the transfer of the foreign gene into a CD4-positive cell of a mammal’ because in light of the teachings of the instant specification this is an inherent property of the claimed MLV-HIV/SIV retroviral vector. The claim is unclear in how this embodiment further limits or defines the vector set forth in claim 13. It is unclear if this embodiment simply sets forth an intended use or somehow attempts to provide an additional functional limitation that appears inherent to the claimed vector set forth in claim 13. It is noted that the remaining portion of the claim encompassing the addition of a “foreign gene” would further limit claim 13 and is not subject to the instant rejection. Deleting this portion of the claim would obviate the basis of the rejection.

Claim 40 recites the limitation “the full-length surface envelope gp120-SU” and “the transmembrane envelope protein resulting from a stop codon at position 712” in lines 2-4. There is insufficient antecedent basis for this limitation in the claim or in claim 13 on which it depends. In addition, it is unclear to what specific sequence and thus to what specific “position 712” refers.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 13-18, 20-22, 28 and 32-35 rejected under 35 U.S.C. 103(a) for the reasons set forth in the Office Action of December 6, 2000 (paper number 15) as being unpatentable over Denesvre *et al.* (J. Virol., 70:4380-4386, 1996), Salmons *et al.* (Leukemia, 9(Suppl.):S53-S60, 1995), Wilk *et al.* (Virology, 189:167-177, 1992) and Zingler *et al.* (J. Virol. 67:2824-2831, 1993) is withdrawn.

Applicants provide a summary of six specific issues discussed in Examiner's rejection and arguments (pages 7-8). Discussing Denesvre *et al.* Applicants summarize the teachings of the cited reference and argue that the teachings are general and that the 'simple rule' suggests making different combinations in general, but it does not anticipate nor provide the specific suggestion or motivation to make obvious the claimed invention. Applicants argue that the teachings of Denesvre *et al.* may provide the artisan motivation to experiment, however this is not sufficient for a *prima facie* case of obviousness (see page 8). Upon consideration of the teachings of Denesvre *et al.* specifically and in the context of the other cited references, Examiner agrees that the while the teachings of Denesvre *et al.* are important to the field in general it does not provide the any specific motivation for the combination present in the retroviral vector as instantly claimed.

With respect to the teachings of Salmons *et al.* Applicants argue that given the guidance the skilled artisan could make a number of type of retroviral vectors, however given the number

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of different strategies for making retroviral vectors, there is no specific motivation to combine retroviral elements as instantly claimed (see pages 8-9). Similar to the teachings of Denesvre *et al.*, Examiner agrees that the general teachings of Salmons *et al.* does not provide adequate motivation to make obvious the combination of the specific elements of the instantly claimed retroviral vector.

With respect to predictability, Applicants argue that the art of record indicates that the reduction to practice of other retroviral vectors demonstrate promising characteristics, however there is no disclosure that any of the characteristics would be to target CD4-positive cells as do the instantly claimed retroviral vectors. This argument is not found persuasive because salmons *et al.* clearly teach that retroviral vectors containing HIV envelope proteins 'principally infects cells expressing the CD4 receptor' (page S58, first column). However, while it would be maintained that vectors comprising full length HIV/SIV envelope proteins would infect CD4 expressing cells and that this would provide motivation to use the HIV envelope protein, there is inadequate motivation to combine a full-length surface envelope protein of HIV/SIV and a truncated transmembrane envelope protein as instantly claimed. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this case, in light of the combined teachings of each of the cited references Examiner would

agree that the general teachings provide an important scientific basis for the instantly claimed retroviral vector, however there is inadequate motivation in a single reference or combination of references that would make obvious the specific combination of elements presently encompassed by the claims.

See Applicants' amendment, pages 8-10. Applicants' arguments have been fully considered, and found persuasive. For the reasons set forth above, the rejection is withdrawn.

Conclusion

Claims 13-18, 21, 22, 32-34, 36-39 are allowed. Claims 20, 28, 35 and 40 are free of the art of record, however they are subject to other rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Voitach whose telephone number is (571) 272-0739.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (571) 272-0734.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (571) 272-0532.

Joseph T. Voitach


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